K050216

AUG 9 - 2005

510(k) Summary of Safety and Effectiveness for the Photo Therapeutics Limited Omnilux Plus

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Photo Therapeutics Limited Station House Stamford New Road Altrincham Cheshire WA14 1EP United Kingdom
Contact Person:	Steve Hutson Director of Engineering and Regulatory Affairs Photo Therapeutics Limited Station House Stamford New Road Altrincham Cheshire WA14 1EP United Kingdom T: +44 161 925 5615 F: +44 161 925 5628
Summary Preparation Date:	December 10th, 2004

2. **Names**

Device Name:	Omnilux Revive and Omnilux Plus Combination
Classification Name:	Omnilux Revive - Laser Instrument, Surgical Powered - General and Plastic Surgery - Class II, 79-GEX Although this device is not a laser, the manufacturer thinks this is the closest applicable classification name. Omnilux Plus – Lamp, Infrared - Physical Medicine - Class II, 89-ILY, 890.5500

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3. Predicate Devices

Predicate devices for the Omnilux Revive and the Omnilux Plus were detailed in K030426 and 510K submission K043317 respectively.

4. Device Description

The Omnilux Revive and Omnilux Plus are two sources of high spectral purity. They provide uniform or "hot-spot" free illumination. The outputs are pre-tuned to one wavelength with a narrow spectral bandwidth. The output of the Omnilux Revive is 633 ± 5 nm, and the output of the Omnilux Plus is 830 ± 5 nm. The base unit contains the power supplies and the control unit. Attached to the base unit are three folding arms. The LED head can be attached to the end of the arms and then positioned for patient treatment. The control unit consists of an LCD and keyboard together with the control electronics. The user interface software allows the operator to access and control all device functions.

5. Indications for Use

The Omnilux Revive and Omnilux Plus Combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

6. Performance Data

Based upon an analysis of the overall performance characteristics for the device, Photo Therapeutics Limited believes that no significant differences exist between the Omnilux Revive and the Omnilux Plus Combination, the previously approved Omnilux Revive (K030426) and the Omnilux Plus (which is the subject of 510K submission K043317). Therefore, the Omnilux Revive and Omnilux Plus Combination raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Mr. Steve Hutson
Director of Engineering and Regulatory Affairs
Photo Therapeutics Limited
Station House, Stamford New Road
Altrincham Cheshire
WA 14 1EP
United Kingdom

Re: K050216
Trade/Device Name: Omnilux Revive and Omnilux Plus Combination
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 16, 2005
Received: June 22, 2005

Dear Mr. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name Omnilux Revive and Omnilux Plus Combination

Indications for Use: K050216

The Omnilux Revive and Omnilux Plus Combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Prescription Use X AND/OR Over The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchnd for Mark Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050216